

## **REMARKS**

### **Formal Matters**

Claims 61-82 were examined. Claims 70-71 and 73-82 were rejected. Claims 61-69 and 72 were allowed. Claims 70-71 and 73 has been amended.

Claims 61-82 are pending after entry of the amendments set forth herein.

Applicants respectfully request reconsideration of the application in view of the amendments and remarks made herein.

Support for the amendment to claims 70-71 and 73 can be found throughout the specification, at, for example, page 5, lines 16-24, page 20, lines 12- 23, and at page 20, line 24 through page 21, line 13. As such, no new matter has been added.

### **Objection to the Specification**

The Examiner has objected to the specification because the specification allegedly refers to a U.S. Patent Application No. (07/847,298) that does not exist. Applicants have amended the specification to delete reference to this application. Therefore, Applicants request withdrawal of this objection.

### **Rejection under 35 U.S.C. § 112, 2<sup>nd</sup> paragraph.**

Claims 70-71 and 73-82 were rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants respectfully traverse the rejection.

The Examiner asserts that claims 70 and 71 are unclear in the recitation of the term “step”. In particular, the Examiner states that it is allegedly unclear how generation of the product recited in step (d) by ligation independent cloning could be accomplished in a single biochemical step. Applicants disagree with the Examiner’s conclusions, and traverse the rejection. Applicants respectfully direct the Examiner’s attention to the specification at, for example, page 20, beginning at line 24, bridging the page. Applicants have described and compared procedures for assembling the targeting construct which require multiple- or single-steps. Applicants describe individually cloning the two homologous sequences (region(s) of homology) into annealing sites within the vector in a

multiple step protocol. Applicants go on to describe a “single-step, four way ligation procedure” for assembling the construct. As a result of treatment of the vector and the homologous sequences to create specific end sequences, only a single step annealing procedure is required to create the desired final construct by ligation independent cloning. Several working examples of each method are also described (see Examples 3-5 for two-step procedures and Examples 6-8 for single step procedures).

The Examiner has suggested the possibility that it would be unclear to the skilled artisan whether cleavage of the selection marker away from the vector would constitute a single step. In claims 70 and 71, Applicants have recited that the “ligation independent cloning” is performed in one or more than one step. As the ligation independent cloning step(s) (described, for example, at page 16, line 9, of the specification) refers to the assembly of the construct and not to cleavage or restriction enzyme cutting of the vector, the skilled artisan would be aware of what step(s) constitutes the ligation independent cloning and, in particular, how the ligation independent cloning could be performed in one biochemical step. This has been well described in the specification, and Applicants submit that the claims, as written, would be clear to the skilled artisan.

Although Applicants respectfully disagree with the Examiner, and traverse the rejection, claims 70-71 have been amended to recite to what the term “step” refers. Applicants submit that the rejection is overcome by this amendment and in light of the remarks above, and respectfully request that the rejection be withdrawn.

The Examiner further asserts that claim 73 is vague and indefinite in the recitation of the phrase “oligonucleotide primers having 5' sequences lacking one type of base”. The Examiner has stated that it is not clear how much of the 5' end of the oligonucleotides must lack a single type of base in order to satisfy this claim limitation. Applicants respectfully traverse the rejection.

Applicants submit that the skilled artisan would be well equipped to determine the number of bases that lack the “one type of base” required in order to create the desired tails, and this is well described in the specification (see, for example, page 5, lines 18-22 or page 20, lines 12-23). However, in light of the amendment to claim 73, the rejection is no longer relevant.

Therefore, Applicants submit that rejections of the above-cited claims under 35 U.S.C. § 112, second paragraph, is overcome in view of the amendments and remarks set forth herein. The Examiner is thus respectfully requested to withdraw these rejections.

**Conclusion.**

Applicants submit that all of the pending claims are in condition for allowance, and notice to that effect is respectfully requested.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-1271.

Respectfully submitted,  
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